DEC 1 8 2001

510(k) Summary
(As Required by 21 C.F.R. §807.92)

K013907

Submitted by: Avril Murray, MSc.
Product Development Manager
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Date of summary: November 23, 2001

Device name: Inverness Medical™ Early Pregnancy Test

Common name: Early Pregnancy Test

Classification names:

Regulation Number	Classification Name
862.1155(a)	Kit, Test, Pregnancy, hCG, Over the Counter

Predicate Device: The modified device is substantially equivalent to the previously cleared Selfcare Early Pregnancy Test (K960436).

Modifications: The primary modifications are changes to the strip width and specimen sample size. Corresponding dimensional changes have been made to the housing to accommodate the narrower strip design.

Intended Use: The modified device has the same intended use as the legally marketed predicate device. The Inverness Medical™ Early Pregnancy Test is intended for use by lay consumers for the qualitative detection of hCG in urine as an aid in the detection of early pregnancy.

Technological Characteristics: The modified device has the same technological characteristics as the legally marketed predicate device employing monoclonal antibodies for immunochromatographic assay.

Testing: Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device. Testing involved safety testing from the risk analysis. Other evaluations included laboratory studies for repeatability, sensitivity, and interferences, and field evaluations for professional and consumer accuracy. Acceptance criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2001

Ms. Avril Murray MSc
Product Development Manager
Cambridge Diagnostics Ireland, Ltd.
Mervue Industrial Estate
Galway,
Ireland

Re: k013907
Trade/Device Name: The Inverness Medical™ Early Pregancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gondotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX;
Dated: November 23, 2001
Received: November 26, 2001

Dear Ms. Murray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number K013907
(if known)

Device Name The Inverness Medical™ Early Pregnancy Test

Indications for Use The Inverness Medical™ Early Pregnancy Test is intended for use by lay consumers for the qualitative detection of hCG in urine as an aid in the detection of early pregnancy.

Thomas E. Dyste for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013907

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)